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5.0 510(k) Summary

Micrus Endovascular Corporation
Micrus® Microcoil Delivery System

FEB 26

This 510(k) Summary for the Micrus® Microcoil Delivery System is submitted in accordance with the requirements of 21 C.F.R. § 807.92.

GENERAL INFORMATION

Manufacturer:
Micrus Endovascular Corporation
821 Fox Lane
San Jose, California 95131
Phone: (408) 433-1400
Est. Registration No. 2954740

Contact Person:
Julia Gross
Director, Regulatory & Clinical Affairs
Phone: (408) 433-1408
Fax: (408) 433-1585
jgross@micruscorp.com

Date Prepared: December 6, 2007

DEVICE CLASSIFICATION

Classification: Class II

Trade Name: Micrus® Microcoil Delivery System

Generic/Common Name: Neurovascular embolization device (21 CFR § 882.5950)
Vascular embolization device (21 CFR § 870.3300)

PREDICATE DEVICES

Micrus® Microcoil Delivery System (reference: K070707)
Micrus® Microcoil Delivery System (reference: K031578)
Boston Scientific / Target Therapeutics, Guglielmi Detachable Coil (reference: K962503)
Cordis Neurovascular, Trufill DCS Detachable Coil (reference: K071962)

INTENDED USE

The Micrus Microcoil Delivery System is intended for endovascular embolization of intracranial aneurysms, other neurovascular abnormalities such as arteriovenous malformations and arteriovenous fistulae, and are also intended for arterial and venous embolizations in the peripheral vasculature.

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DEVICE DESCRIPTION

The Micrus Microcoil System each consist of an embolic coil ("Microcoil") attached to a Device Positioning Unit (DPU) (single use, sterile).

SUBSTANTIAL EQUIVALENCE

The previously cleared Micrus Microcoil Delivery System is substantially equivalent to the Boston Scientific / Target Therapeutics Guglielmi Detachable Coil and the Cordis Neurovascular Trufill DCS Detachable Coil systems in terms of intended use, design, specifications, and materials. These systems are all intended for use in the embolization of aneurysms. The predicate devices have additional indications in their labeling; specifically, embolization in the peripheral vasculature. The Micrus Microcoil Delivery System uses the same methods and materials in construction, packaging, and sterilization as its predicates. The modification to the intended use statement has not altered the fundamental technology of the Micrus devices.

CONCLUSION

As described in this 510(k) Summary, Micrus Endovascular Corporation considers the Micrus® Microcoil Delivery System to be substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 26 2008

Micrus Endovascular Corporation
% Ms. Julia Gross
Director, Regulatory and Clinical Affairs
821 Fox Lane
San Jose, California 95131

Re: K073442
Trade/Device Name: Micrus Microcoil Delivery Systems
Regulation Number: 21 CFR 882.5950
Regulation Name: Neurovascular embolization device
Regulatory Class: II
Product Code: HCG
Dated: December 6, 2007
Received: December 7, 2007

Dear Ms. Gross:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K073442

4.0 Indications for Use

510(k) Number (if known): _____

Device Name: Micrus Microcoil Delivery Systems

Indications For Use:

The Micrus Microcoil Delivery System is intended for endovascular embolization of intracranial aneurysms, other neurovascular abnormalities such as arteriovenous malformations and arteriovenous fistulae, and are also intended for arterial and venous embolizations in the peripheral vasculature.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mark N Millans

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K073442